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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/643,797	LANGLOIS ET AL.
	Examiner	Art Unit
	Nelson Yang	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,12,15,16,19,27,29 and 31-50* is/are pending in the application.

4a) Of the above claim(s) *41-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,12,15,16,19,27,29 and 31-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1, 3, 12, 15, 16, 19, 29, 31, is acknowledged and has been entered.

2. Applicant's cancellation of claims 6-11, 13-14, 17-18, 20-26, 28, and 30 is acknowledged and has been entered.

3. 1-5, 12, 15, 16, 19, 27, 29, 31-50 are pending. Claims 41-50 have been withdrawn.

4. Claims 1-5, 12, 15, 16, 19, 27, 29, 31-40 are currently under examination.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-4, 12, 27, 29, 31-35, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles et al. [US 6,576,459] in view of Casey et al. [US 2002/0187470] and in view of Lawless et al. [US 4,923,491].

With respect to claim 1, Miles et al. teach a sample preparation and analysis device comprising an aerosol collector (column 4, lines 26-28), a filtering device sensitive to density and size differences between particles (column 4, lines 30-35), and mixing the particles with antibody coated beads using an ultrasonic mixer (sample preparation means) (column 4, lines 40-45) for analysis by a detector (flow cytometer, column 4, lines 63-65). Miles et al. further teach a

flow cytometer for analysis of the antibody coated beads (column 4, lines 26-28), which would be capable of functioning as a multiplex immunoassay or PCR detector. Miles et al. fail to teach that the use of optically encoded microbeads imbedded with precise ratios of red and orange fluorescent dyes yielding an array of beads, each with a unique spectral address and coated with capture antibodies specific for a given antigen, and also fails to teach an aerosol collector that is a wetted wall cyclone collector that concentrates said potential bioagent particles in a liquid.

Casey et al., however, teach optically encoded microparticles comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence (para. 0256), which would make multiplexed assays involving multiple analytes, such as multiplexed genotyping of SNPs, possible (para. 0256). Casey et al. further teach that the reporter molecules or haptens may be conjugated by means of a hapten-recognizing intermediary such as antibodies (para. 0065).

Lawless et al. further teach aerosol concentrator assembly comprising a two stage system of concentric components to remove large interfering particles and retain small particles for collection and analysis, where a large outer cyclone is used to separate particles and an inner bank of mini-cyclones is used to capture and concentrate particles, wherein particle-laden gas is pulled through the at least one cyclone chambers by a blower so that the particles are separated from the gas by centrifugal force and collected by the liquid supplied to the at least one cyclone chambers (column 3, lines 5-30). Lawless further teach that this system is extremely flexible and adaptable for a wide range of possible applications that can be integrated with detector technologies (column 4, lines 7-20). Furthermore, the device is a small and efficient means to separate, capture and concentrate bioparticles from the air for detection (column 2, lines 45-48).

Therefore, it would have been obvious to one of ordinary skill art at the time of the invention to have used optically encoded microparticles comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence in the apparatus of Miles et al., as suggested by Casey et al. as the beads of Miles et al., in order allow for a greater number of labels, which would allow for multiplexed assays that would allow for a greater number of analytes to be detected. It would have further been obvious to one of ordinary skill in the art at the time of the invention to use the aerosol concentrator of Lawless et al. comprising a cyclone concentrator in the device of Miles et al., in order to utilize a small and efficient means to separate, capture and concentrate bioparticles from the air for detection.

2. With respect to claim 2, Miles et al. teach a sample preparation and analysis device comprising an aerosol collector (column 4, lines 26-28).

3. With respect to claims 3-4, Miles et al. teach a filtering device sensitive to density and size differences between particles, wherein large particles and dense particles will be transferred to waste (column 4, lines 30-35).

4. With respect to claim 12, Miles et al. teach an ultrasonic fractionation device (lysing means, column 4, lines 30-32, 55-65).

5. With respect to claim 27, Miles et al. teach 1-10 μm sized polystyrene beads (column 3, lines 28-31).

6. With respect to claim 29, 33, 40, Miles et al. teach a flow cytometer for analysis of the antibody coated beads (column 4, lines 26-28), which would be capable of functioning as a multiplex immunoassay or PCR detector for analyzing optically encoded microbeads, such as those of Casey et al.

7. With respect to claim 30, Casey et al. teach optically encoded microparticles comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence (para. 0256); which would make multiplexed assays involving multiple analytes, such as multiplexed genotyping of SNPs, possible (para. 0256).

8. With respect to claim 31, 32, 34, 35, Miles et al. further teach a flow cytometer for analysis of the antibody coated beads (column 4, lines 26-28), which would be capable of functioning as a multiplex immunoassay or PCR detector.

9. Claims 1, 15-16, 19, 33, 36-39 are rejected are rejected under 35 U.S.C. 103(a) as being unpatentable over Colston, Jr. et al. [US 2003/0032172] in view of Casey et al. [US 2002/0187470] and in view of Lawless et al. [US 4,923,491].

With respect to claim 1, Colston, Jr. et al. teach a nucleic acid assay system for analyzing a sample (other substance) using a reagent comprising a holding means that receives the sample and the reagent, a PCR reactor means that amplifies the sample and produces an amplified sample, a detection means detects PCR amplicon, a transport means selectively transports the sample, the reagent, and the amplified sample relative to the holding means, the PCR reactor means, and the detection means, wherein the transport means is operatively connected to the holding means, the PCR reactor means, and the detection means (para. 0019). Colston, Jr. et al. further teach control means is provided for selectively adding the reagent to the sample, mixing the sample and the reagent, performing PCR amplification, and detecting PCR amplicon and a decontamination means is provided for decontaminating the holding means, the PCR reactor means, and the detection means (para.0019). Colston, Jr. et al. fail to teach that the use of optically encoded microbeads imbedded with precise ratios of red and orange fluorescent dyes

yielding an array of beads, each with a unique spectral address and coated with capture antibodies specific for a given antigen, and also fails to teach an aerosol collector that is a wetted wall cyclone collector that concentrates said potential bioagent particles in a liquid.

Casey et al., however, teach optically encoded microparticles comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence (para. 0256), which would make multiplexed assays involving multiple analytes, such as multiplexed genotyping of SNPs, possible (para. 0256).

Lawless et al. further teach aerosol concentrator assembly comprising a two stage system of concentric components to remove large interfering particles and retain small particles for collection and analysis, where a large outer cyclone is used to separate particles and an inner bank of mini-cyclones is used to capture and concentrate particles, wherein particle-laden gas is pulled through the at least one cyclone chambers by a blower so that the particles are separated from the gas by centrifugal force and collected by the liquid supplied to the at least one cyclone chambers (column 3, lines 5-30). Lawless further teach that this system is extremely flexible and adaptable for a wide range of possible applications that can be integrated with detector technologies (column 4, lines 7-20). Furthermore, the device is a small and efficient means to separate, capture and concentrate bioparticles from the air for detection (column 2, lines 45-48).

Therefore, it would have been obvious in the apparatus of Colston, Jr. et al. to have used optically encoded microparticles comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence, as suggested by Casey et al. for labeling the analytes of Colston, Jr. et al., in order allow for a greater number of labels, which would allow for multiplexed assays that would allow for a greater number of analytes to be detected. It would have further been

obvious to one of ordinary skill in the art at the time of the invention to use the aerosol concentrator of Lawless et al. comprising a cyclone concentrator in the device of Colston, Jr. et al., in order to utilize a small and efficient means to separate, capture and concentrate bioparticles from the air for detection.

10. With respect to claim 15, Colston, Jr. et al. teach a sequential injection analysis system (para. 0036).

11. With respect to claim 16, Colston, Jr. et al. teach a means for injecting and or aspirating a sample provides injection and/or aspiration of the sample (para. 0041).

12. With respect to claim 19, Colston, Jr. et al. teach a super serpentine reactor (para. 0047).

13. With respect to claim 20, Colston, Jr. et al. teach mixing means (para. 0039) and transport means (para. 0019).

14. With respect to claims 33, 36, Colston, Jr. et al. teach real time PCR detection (para. 0055).

15. With respect to claim 37, Colston, Jr. et al. teach a PCR reactor means that amplifies the sample and produces an amplified sample (para. 0019).

16. With respect to claims 38-39, Colston, Jr. et al. teach a nucleic acid assay system for analyzing a sample using a reagent comprising a holding means that receives the sample and the reagent, a PCR reactor means that amplifies the sample and produces an amplified sample, a detection means detects PCR amplicon, a transport means selectively transports the sample, the reagent, and the amplified sample relative to the holding means, the PCR reactor means, and the detection means, wherein the transport means is operatively connected to the holding means, the PCR reactor means, and the detection means (para. 0019). Colston, Jr. et al. further teach control

means is provided for selectively adding the reagent to the sample, mixing the sample and the reagent, performing PCR amplification, and detecting PCR amplicon and a decontamination means is provided for decontaminating the holding means, the PCR reactor means, and the detection means (para.0019).

17. Claims 1-5, 32, 33, 35-37 are rejected are rejected under 35 U.S.C. 103(a) as being unpatentable over Daugherty et al. [US 2004/0028561] in view of Casey et al. [US 2002/0187470].

With respect to claim 1, Daugherty et al. teach a bio-hazard collection and testing system comprising a collection subsystem for collecting particles in on and around mail (substance being monitored), a filtration subsystem for separating the bio-hazardous sized particles from collected particles for testing, a sampling subsystem for preparing a sample containing the bio-hazardous particles, and an analysis subsystem for determining the composition of the biohazardous particles in the analysis sample (para. 0007). Daugherty et al. fail to teach that the use of optically encoded microbeads imbedded with precise ratios of red and orange fluorescent dyes yielding an array of beads, each with a unique spectral address and coated with capture antibodies specific for a given antigen, and also fails to teach an aerosol collector that is a wetted wall cyclone collector that concentrates said potential bioagent particles in a liquid.

Casey et al., however, teach optically encoded microparticles comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence (para. 0256), which would make multiplexed assays involving multiple analytes, such as multiplexed genotyping of SNPs, possible (para. 0256).

Lawless et al. further teach aerosol concentrator assembly comprising a two stage system of concentric components to remove large interfering particles and retain small particles for collection and analysis, where a large outer cyclone is used to separate particles and an inner bank of mini-cyclones is used to capture and concentrate particles, wherein particle-laden gas is pulled through the at least one cyclone chambers by a blower so that the particles are separated from the gas by centrifugal force and collected by the liquid supplied to the at least one cyclone chambers (column 3, lines 5-30). Lawless further teach that this system is extremely flexible and adaptable for a wide range of possible applications that can be integrated with detector technologies (column 4, lines 7-20). Furthermore, the device is a small and efficient means to separate, capture and concentrate bioparticles from the air for detection (column 2, lines 45-48).

Therefore, it would have been obvious in the apparatus of Daugherty et al. to have used optically encoded microparticles comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence, as suggested by Casey et al. for labeling the analytes of Daugherty et al., which would allow for multiplexed assays that would allow for a greater number of analytes to be detected. It would have further been obvious to one of ordinary skill in the art at the time of the invention to use the aerosol concentrator of Lawless et al. comprising a cyclone concentrator in the device of Daugherty et al., in order to utilize a small and efficient means to separate, capture and concentrate bioparticles from the air for detection.

18. With respect to claim 2, Daugherty et al. teach a concentrating the particles using a conventional aerosol concentrator (para. 0032).

19. With respect to claims 3, Daugherty et al. teach a filtration subsystem (separator means) for separating the bio-hazardous sized particles from collected particles for testing (para.007).

20. With respect to claims 4, Daugherty et al. teach a filtration subsystem (separator means) for separating the bio-hazardous sized particles (separation based on predetermined size) from collected particles for testing (para. 0007).

21. With respect to claim 5, Daugherty et al. teach a filtering means wherein unfiltered air is first captured by a set of pitot tubes, pre-filtered, and transported to the triggering and sampling subsystems (para.007). As previously described, prefilter allows the large particles to pass into main air flow (bypass air flow), while retaining the smaller particles which are captured by the prefilter at inlet flow (FIG. 7B) and passed to receiving probe, where air and particles exit the receiving probe as minor flow (product air flow).

22. With respect to claims 32, 33, 35, 37, the sampling subsystem prepares a liquid sample suitable for conventional bioassay test strip analysis, conventional polymerase chain reaction (PCR) analysis (nucleic acid assays sample) (para. 0032).

23. With respect to claim 36, the sampling subsystem prepares a liquid sample suitable for conventional bioassay test strip analysis, conventional polymerase chain reaction (PCR) analysis (nucleic acid assays sample) (para. 0032). Daugherty et al. further teach that the analysis subsystem can execute in real-time (para. 0011).

Response to Arguments

24. Applicant's arguments with respect to claims 1-5, 12, 15, 16, 19, 27, 29, 31-40 have been considered but are moot in view of the new ground(s) of rejection. Applicant's arguments that

there are no suggestion or motivation to combine and no reasonable expectation of success, however, are addressed.

25. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Casey et al., however, teach optically encoded microparticles comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence (para. 0256), which would make multiplexed assays involving multiple analytes, such as multiplexed genotyping of SNPs, possible (para. 0256), which would allow for multiplexed assays capable of detecting a greater number of analytes.

26. With respect to the argument of no reasonable expectation of success, Miles et al. further teach a flow cytometer for analysis of the antibody coated beads (column 4, lines 26-28), and would therefore be capable of analyzing the beads of Casey et al. Furthermore, the systems of Daugherty et al. and Colston, Jr. et al. utilize optical fluorescent detection, and therefore would be capable of detecting the fluorescently encoded beads of Casey et al.

27. For these reasons applicant's arguments are not found persuasive.

Conclusion

28. No claims are allowed.

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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